K080786 p. 1 of 2

APPENDIX D

OCT - 3 2008

SUMMARY OF SAFETY AND EFFICACY

510(k) PREMARKET NOTIFICATION SUMMARY
(per 21 CFR 807.92)

ML830®TP – PRELIMINARY STATEMENT

I. Applicant:

MicroLight Corporation of America
2935 Highland Lakes Drive
Missouri City, Texas 77459

Contact Person: Fred A. Simpson, Esq.
c/o Jackson Walker L.L.P.
713-752-4248 telephone
713-752-4221 facsimile
e-mail fsimpson@jw.com

Date Prepared: March 18, 2008

II. Device Name

Proprietary Name:	**ML830®TP**
Common / Usual Name:	Infrared Lamp
Classification Name:	Infrared Lamp (21 CFR 890.550)
Product Code:	ILY

III. Predicate Device

The ML830®TP is substantially equivalent to other single diode infrared lamps currently in commercial distribution such as the Powerlaser by Powermedic APS which is the subject of a clearance letter from the Agency under 510(k) number **K070516**, which itself was predicated on the PowerLaser 90, the subject of **K030692**. In addition, or in the alternative, the ML830®TP is substantially equivalent to the Thor VR Single Diode Laser Treatment Probe which is the subject of a clearance letter from the Agency under 510(k) **K070024**..

These three predicate devices were cleared by the Agency for introduction into interstate commerce by means of the FDA's 510(k) notification process.

IV. Intended Use of the Device

The ML830®TP is intended to emit energy in the visible and near infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation; and the temporary relaxation of muscles.

V. Description of the Device

The **ML830®TP** is a non-invasive, easy to use hand-held therapeutic device consisting of a probe containing battery-powered electronics that activate a single diode which delivers infrared energy. The probe is intended to be placed on or near the surface of the skin to provide temporary relief from pain.

VI. Summary of the technical characteristics of the ML830®TPto the referenced predicate devices.

The **ML830®TP** and the aforementioned predicate devices are non-heating lamps, as defined in 21 CFR 890.5500. These devices utilize infrared and laser diodes to generate topical hearing for the purpose of elevating tissue temperatures for temporary relief of muscle and joint pain.

VII. Testing

Testing of the **ML830®TP** will include functional performance testing, functional performance testing, and electrical safety testing in accordance with all applicable standards for this type of medical device.

VIII. Sterility – Packaging Description

The **ML830®TP** is not intended to be sterilized, but the contact surface may be cleaned with a cloth moistened with 70% isopropal alcohol. The devise is delivered in a styrofoam container and metal box which may be used as a protective carrying case during the economic life of the device.

IX. Conclusions

Pursuant to the testing and substantial comparison with the predicate devices, the **ML830®TP** has the same intended uses, with similar functional and performance characteristics as those predicate devices listed in Section III above. The **ML830®TP** is designed to comply with the generally accepted therapeutic heat performance specifications by producing a level of tissue temperature as reported in literature and accepted by the U.S. Food & Drug Administration.

The ML830®TP is manufactured and performs as intended and does not raise any new safety or efficacy issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MicroLight Corporation of America
c/o Fred A. Simpson, Esq.
Jackson Walker L.L.P.
1401 McKinney Street, Suite 1900
Houston, Texas 77010

OCT - 3 2008

Re: K080786
Trade/Device Name: ML830® TP
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: ILY September 30, 2008
Received: October 1, 2008

Dear Mr. Simpson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K080786 p. 1 of 1

APPENDIX C

STATEMENT OF INDICATIONS FOR USE

510(k) Number: K080786

Device Name: ML830®TP

Indications for Use: MicroLight Corporation of America's ML830®TP is intended to emit energy in the visible and near infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation; and the temporary relaxation of muscles.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ **(Per 21 CFR 801.109)** OR **Over the Counter Use:** **(Optional Format 1-2-96)**

(Division Sign-Off)

510(k) Number K080786

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080786